The opinion in support of the decision being entered today was ***not*** written for publication and is ***not*** binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

MAILED

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U.S. PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEVEN Y. NG
and JORGE HELLER

Appeal No. 2005-0590
Application 09/854,435

ON BRIEF

Before KIMLIN, WARREN and KRATZ, *Administrative Patent Judges*.

WARREN, *Administrative Patent Judge*.

Decision on Appeal

This is an appeal under 35 U.S.C. § 134 from the decision of the examiner finally rejecting claims 1 through 14 and 17 through 19. Claims 20 through 35 are also of record and have been withdrawn from consideration by the examiner under 37 CFR § 1.142(b).

Claim 1 illustrates appellants' invention of a polyorthoester, depicted by the structural formula set forth in this claim, which polymers are disclosed to be bioerodible and thus useful in, for example, orthopedic implants and vehicles for controlled release drug delivery (specification, e.g., pages 5-6). A copy of appealed claim 1 taken from appellants' brief is appended to this decision.

The references relied on by the examiner are:

Sparer et al. (Sparer)	4,549,010	Oct. 22, 1985
Heller et al. (Heller)	5,968,543	Oct. 19, 1999

The examiner has rejected appealed claims 1 through 14 and 17 through 19 under 35 U.S.C. § 103(a) as being unpatentable over Heller combined with Sparer (answer, page 3).[1]

Appellants state that they "will argue the patentability of appealed claims 1-14 and 17-19 together" (brief, page 3). Thus, we decide this appeal based on appealed claim 1. 37 CFR § 1.192(c)(7) (2003); *see also* 37 CFR § 41.37(c)(1)(vii) (effective September 13, 2004; 69 Fed. Reg. 49960 (August 12, 2004); 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)).

We affirm.

Rather than reiterate the respective positions advanced by the examiner and appellants, we refer to the answer and to the brief for a complete exposition thereof.

Opinion

The review of the ground of rejection of claim 1 requires that we first interpret this claim by giving the language thereof the broadest reasonable interpretation in light of the written description in appellants' specification as it would be interpreted by one of ordinary skill in this art, without reading into the claim any limitation or particular embodiment disclosed in the specification. *See In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); *In re Priest*, 582 F.2d 33, 37, 199 USPQ 11, 15 (CCPA 1978). The structural formulae and accompanying formula member and subscript definitions depict any polyorthoester falling within formula (I), wherein formula member "A" must be "R^1" and "R^4" to the extent of "at least 0.1 mol% of

[1] The examiner states that the ground of rejection is set forth in the prior Office action mailed February 26, 2003. At page 2 of this Office action, the examiner refers to the prior Office action mailed September 27, 2002. While the examiner has not stated the ground of rejection in the answer or incorporated the ground of rejection from a single prior Office action as permitted by the practice in Manual of Patent Examining Procedure §§ 1208 (8th ed., Rev. 2, May 2004; 1200-17), we will not in this instance remand the application to the examiner for the purpose of preparing a supplemental examiner's answer to cure this deficiency because we find consistent statements of the ground of rejection in the above two Office actions, and so have considered the ground of rejection advanced on appeal.

the A units," with no further limitation on the number of units of each of the components "A is R^1, R^1, R^1, or R^1" selected to constitute 100 mol% of the "A units," and wherein subscript "n" is the range of "units" or "segments" in a polyorthoester chain of "at least 5" to no specified upper limit. We note that there is no limitation on the manner in which the claimed polyorthoesters are prepared, and thus the claimed polyorthoesters include block as well as random distribution of the "units" or 'segments" in the polymer chain. *See generally, In re Thorpe*, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985).[2]

We find that Sparer would have disclosed to one of ordinary skill in this art polyorthoester polymers which are prepared by reacting a diketene acetal with certain diols, wherein the diols are reacted either separately, to form a block copolymer, or in admixture, to form a random polymer (e.g., col. 1, ll. 33-35, and col. 4, ll. 36-45). One of ordinary skill in this art routinely following the teachings of Sparer would have arrived at polyorthoesters which contain units that correspond to "A units" "R^2," "R^3" and "R^4" of structural formula (I) of appealed claim 1, wherein the units are hard or rigid units, flexible or soft units, and hard or rigid units, respectively, and unit "R^4" is a hydrogen bonding unit containing at least one amide, imide, urea and urethane group (e.g., col. 2, l. 42, to col. 3, l. 43, col. 3, l. 65, col. 4, ll. 13-19). The amounts of and arrangement of the respective units in the polyorthoesters are disclosed to be based on the properties desired for bioerodibility and in the fabrication of medical devices, such as implants, and controlled release drug delivery forms, wherein the polymer can be cross-linked (e.g., col. 1, ll. 7-22 and 34-68, col. 2, ll. 2-28, col. 4, ll. 16-45). Thus, because the hydrogen bonding unit can be present at least in some amount, the polyorthoesters of Sparer differ from the

[2] We note, in this respect, that appealed claim 17 is drawn to a method of preparing a claimed polyorthoester wherein a diketene diacetal is reacted with at least two and optionally more *diols* without specifying whether the diols are reacted with the diketene acetal separately, resulting in a block polymer, or in mixtures, resulting in a random polymer. *See also* specification, e.g., page 13, l. 23, to page 14, l. 2, and page 16, l. 27, to page 17, l. 2. In contrast, appealed claims 18 and 19 are couched in product-by-process format wherein the claimed polyorthoester product is characterized as being prepared by the reaction of a diketene diacetal and a *polyol* or mixture of *polyols* even though diols are structurally depicted and specified in these claims. *See Thorpe, supra*. We interpret claims 18 and 19 to encompass random or block polyorthoesters encompassed by appealed claim 1.

claimed polyorthoesters encompassed by claim 1 in the absence of unit(s) corresponding to "A unit" "R^1," that is, wherein "A" is derived from an α-hydroxyacid containing diol to provide units of the structure shown in the claim 1 (specification, e.g., page 5, ll. 19-21).

We further find that Heller would have disclosed polyorthoester polymers which are prepared from a diketene acetal and a mixture of diols to form a random polymer (e.g., col. 2, ll. 11-22, col. 5, l. 18, to col. 7, l. 63, and col. 8, l. 52, to col. 9, l. 26). One of ordinary skill in this art routinely following the teachings of Heller would have arrived at polyorthoesters which contain units that correspond to "A units" "R^1," "R^2" and "R^3" to provide units of the structure shown in of structural formula (I) of appealed claim 1, wherein the former unit is derived from an α-hydroxyacid containing diol and the latter two units are hard or rigid units and flexible or soft units, respectively, and (e.g., col. 5, l. 58, to col. 6, l. 32, col. 6, l. 33 and 45-65, and col. 4, ll. 1 and 11-27). The amounts of and arrangement of the respective units in the polyorthoesters are disclosed to be based in the properties desired for bioerodibility and in the fabrication of medical devices such as implants, and controlled release drug delivery forms, wherein the polymer can be cross-linked (e.g., col. 1, ll. 16-22, col. 2, ll. 12-18, col. 5, ll. 31-32, col. 7, ll. 55-67, and col. 10, ll. 15-54). Thus, because the units is derived from α-hydroxyacid containing diols can be present at least in some amount, the polyorthoesters of Heller differ from the claimed polyorthoesters encompassed by claim 1 in the absence of unit(s) corresponding to "A unit" "R^4," that is, hydrogen bonding unit(s) containing at least one amide, imide, urea and urethane group.

The examiner finds that, *prima facie*, one of ordinary skill in the art would have modified the polyorthoester polymers of Heller by using the hydrogen bonding unit(s) containing at least one amide, imide, urea and urethane group as taught by Sparer in the expectation of obtaining bioerodible polyorthoester polymers, pointing out that the polyorthoesters of each reference are prepared in the same manner from diketene acetals and diols (Office action, mailed September 27, 2002; pages 2-3; see also answer, pages 3-4).

We find in the combined teachings of Heller and Sparer substantial evidence supporting the examiner's position with respect to appealed claim 1 as we have interpreted this claim above. We determine that in view of the common polyorthoester chemical structure, the common bioerodible-based utility, the common method of preparation as random polymers, and the

common direction in these references to use the same type of groups that provide bioerodibility to the polyorthoesters for purposes of the common utility, there is in the combined teachings of Heller and Sparer ample direction to one of ordinary skill in this art to use the hydrogen bonding units of Sparer in the polyorthoesters of Heller in the reasonable expectation of obtaining bioerodible polyorthoester polymers having the same or similar properties, as submitted by the examiner. Indeed, we find that these same facts provide substantial support for the position that, *prima facie*, one of ordinary skill in this art would have modified the polyorthoesters of Sparer by using the α-hydroxyacid containing unit(s) taught by Sparer in the reasonable expectation of obtaining bioerodible polyorthoester polymers having the same or similar properties.

Accordingly, we are convinced that, *prima facie*, one of ordinary skill in this art routinely following the combined teaching of Heller and Sparer would have reasonably arrived at the claimed polyorthoester polymers encompassed by claim 1, without resort to the written description in appellants' specification. *See In re Payne*, 606 F.2d 303, 315, 203 USPQ 245, 254-55 (CCPA 1979) ("An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties."); *see also In re Dillon*, 919 F.2d 688, 692-93, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990)(*in banc*) ("This court . . . reaffirms that structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness, and that the burden (and opportunity) then falls on an applicant to rebut that *prima facie* case."); *In re Grabiak*, 769 F.2d 729, 731-32, 226 USPQ 870, 872 (Fed. Cir. 1985) ("[W]e have concluded that generalizations should be avoided insofar as specific chemical structures are alleged to be *prima facie* obvious one from the other. . . . [I]n the case before us there must be adequate support in the prior art for the ester/thioester change in structure, in order to complete the PTO's *prima facie* case and shift the burden of going forward to the applicant.").

We have determined that the examiner has advanced a *prima facie* case of obviousness and thus, we again evaluated all of the evidence of obviousness and nonobviousness based on the record as a whole in light of appellants' rebuttal arguments in the brief. *See generally, In re*

Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984).

Appellants submit that the examiner has not established a *prima facie* case of obviousness because one of ordinary skill in the art would not look to Sparer to modify Heller, contending that this person would have understood that Heller is "directed to a random copolymer," and while Sparer "does permit random copolymerization," that for Sparer to "achieve the stated goal of providing a thermoplastic elastomer, the poly(ortho ester) can not be a random copolymer but must be a block copolymer" (brief, page 5). Thus, appellants argue that no reason has been advanced for making the proposed modification.

In order to render the claimed polyorthoesters obvious within the meaning of § 103(a), the combined teachings of Heller and Sparer must provide an enabling disclosure that places the claimed polyorthoesters in the possession of the public. *Payne*, 606 F.2d at 314, 203 USPQ at 255. Here, as we found above, Sparer discloses the preparation of *random* polyorthoester polymers as does Heller. Appellants' contrary allegations that one of ordinary skill in this art would necessarily have to form a *block* copolymer to obtain the thermoplastic elastomeric polyorthoesters of Sparer are unsupported and thus, are entitled to little, if any, weight, particularly since appellants' position, in this respect, encompasses the allegation that Sparer does not operably enable the random polyorthoester polymers encompassed by, e.g., Sparer patent claim 1. *See Payne*, 606 F.2d at 315, 203 USPQ at 256; *In re Lamberti*, 545 F.2d 747, 751, 751 n.2, 192 USPQ 278, 281, 281 n.2 (CCPA 1976); *In re Weber*, 405 F.2d 1403, 1406-07, 160 USPQ 549, 552-53 (CCPA 1969).

We find that appellants have failed to carry the burden of establishing the patentability of the claimed polyorthoester polymers encompassed by appealed claim 1 over the combined teachings of Heller and Sparer by presenting effective argument or objective evidence establishing that the claimed polyorthoester polymers possess unexpectedly advantageous or superior properties. *See Payne*, 606 F.2d at 315, 203 USPQ at 256.

Accordingly, based on our consideration of the totality of the record before us, we have weighed the evidence of obviousness found in the combined teachings of Heller and Sparer with appellants' countervailing evidence of and argument for nonobviousness and conclude that the

claimed invention encompassed by appealed claims 1 through 14 and 17 through 19 would have been obvious as a matter of law under 35 U.S.C. § 103(a).

The examiner's decision is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a)(1)(iv) (effective September 13, 2004; 69 Fed. Reg. 49960 (August 12, 2004); 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)).

AFFIRMED

EDWARD C. KIMLIN)
Administrative Patent Judge)
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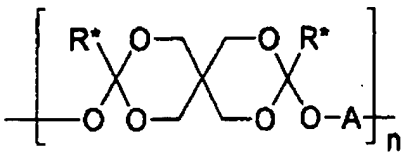
CHARLES F. WARREN) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
) INTERFERENCES
)
)
PETER F. KRATZ)
Administrative Patent Judge)

Appendix

1. A polyorthoester of formula I:



(I)

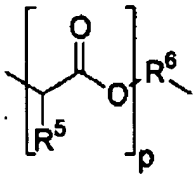
where:

R* is a C_{1-4} alkyl;

n is an integer of at least 5; and

A is R^1, R^2, R^3, or R^4, where

R^1 is:

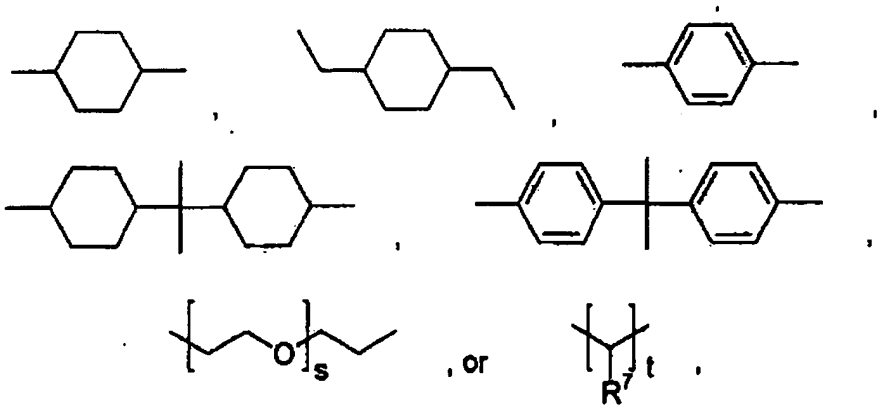


where:

p is an integer of 1 to 20;

R^5 is hydrogen or C_{1-4} alkyl; and

R^6 is:



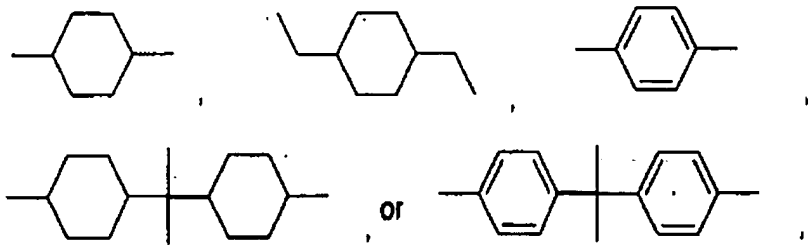
where:

s is an integer of 0 to 30;

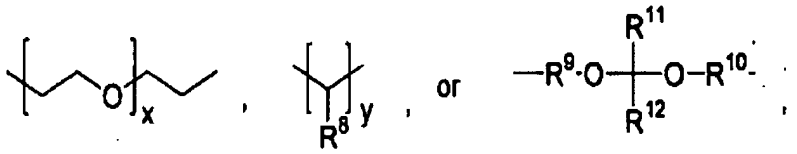
t is an integer of 2 to 200; and

R^7 is hydrogen or C_{1-4} alkyl;

R^2 is:



R^3 is:



where:

x is an integer of 0 to 30;

y is an integer of 2 to 200;

R^8 is hydrogen or C_{1-4} alkyl;

R^9 and R^{10} are independently C_{1-12} alkylene;

R^{11} is hydrogen or C_{1-6} alkyl and R^{12} is C_{1-6} alkyl; or R^{11} and R^{12} together are C_{3-10} alkylene; and

R^4 is a diol containing at least one functional group independently selected from the group consisting of amide, imide, urea, and urethane groups;

in which at least 0.1 mol% of the A units are R^1, and at least 0.1 mol% of the A units are R^4.

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